

## **REMARKS**

Claims 1-19 are presently pending in the application. Claims 1-19 are rejected. The specification and drawings stand as filed.

Reconsideration of the objections and rejections set forth in the aforementioned Office Action is respectfully requested in view of the following remarks. The basis for the amendments can be found throughout the Specification, Claims and Drawings as originally filed.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lecuyer et al. (USPN 5,843,013) in view of Hooven (USPN 4,676,772). This rejection is respectfully traversed.

The Applicant respectfully submits that none of the references cited by the Examiner, either solely or in combination with one another, render claim 1 obvious. Claim 1 recites a rod with a variable cross-section arranged to enter an orifice of a separation membrane as well as a means of axial movement of means supporting the rod. Claim 1 also recites a drive means for driving the movement means so as to allow the adjustment of the flow rate of the valve in a non-invasive manner. The Applicant respectfully submits that none of the references provided by the Examiner, either solely or in combination with one another, teach or suggest the claimed combination of elements. On the contrary, Lecuyer et al. USPN 5,843,013 discloses a rod 23 being at a fixed location and being non-moveable. In particular, Col. 3, line 34 states that a resin 24 holds the rod 23 in the bore 22. Furthermore, none of the references cited by the

Examiner provide a drive means to allow adjustment of the **flow rate of the valve**. As previously stated, Lecuyer et al. does not provide for adjustment of the valve in a non-invasive manner as claimed. Hooven adjusts the valve's opening threshold pressure setting as stated in the abstract of the '772 reference and acts as a pressure relief valve as stated in claim 1 of the Hooven reference. Adjusting the flow rate of the valve is not taught or suggested. Accordingly, the Applicant respectfully requests withdrawal of the § 103 rejections to claims 1-5.

Regarding claim 6, the Applicant respectfully submits that none of the references cited, either solely or in combination with one another, render claim 6 obvious. In particular, claim 6 recites the previously discussed elements of a rod with a variable cross-section arranged to enter an orifice of a separation membrane, and means for axial movement of the means supporting the rod. Furthermore, claim 6 recites that the movement means comprises a lever mounted on the housing and in abutment on the rod support means, the lever cooperating with cam means of the drive means.

None of the references cited by the Examiner teach or suggest a valve including each of the elements of presently pending claim 6. In particular, Lecuyer et al. does not disclose any drive means for driving the movement means at all, because rod 23 is a fixed member. In addition, Hooven lacks any teaching or suggestion relating to a lever in abutment on means supporting a rod where the lever cooperates with cam means of the drive means. On the contrary, Hooven discloses a threaded member providing a seat for a spherically shaped ball. The position of the ball may be varied by rotation of the threaded member. As such, no lever or cam is taught or suggested. Therefore, the

Applicant respectfully requests withdrawal of the § 103 rejections relating to claims 6-18.

Regarding claim 19, the Applicant submits that none of the references cited by the Examiner, either solely or in combination with one another, render claim 19 obvious. In particular, claim 19 recites a rod with a variable cross-section arranged so as to axially enter an orifice of a separation membrane. A rod support is axially moveable and a driver operably causes the axial movement. The driver is arranged so as to be activated from outside a patient to allow adjustment of the flow rate of the valve in a non-invasive manner. As previously discussed, the Applicant submits that none of the references cited by the Examiner teach or suggest this combination of elements. On the contrary, Lecuyer et al. discloses a rod having a fixed position, lacks any discussion regarding a driver to axially move the rod support and further lacks discussion allowing adjustment of the flow rate of the valve from the outside of a patient in a non-invasive manner. Similarly, Hooven does not disclose a driver arranged to be activated from outside of a patient to allow adjustment of the **flow rate** of a valve in a non-invasive manner. On the contrary, Hooven provides for adjustment of the valve's opening threshold pressure setting.

Accordingly, the Applicant respectfully submits that a *prima facie* case of obviousness has not been made. In particular, each and every element of the rejected claims has not been taught or suggested by the cited prior art. Furthermore, the Applicant respectfully submits that the Examiner has not identified a reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Lecuyer et al. provides a valve having a fixed rod where the flow rate

of the valve is not adjustable after being implanted in a patient. Hooven does not teach to make a variable cross-section rod moveable. On the contrary, Hooven teaches the use of a closure ball 29 placed in biased engagement with a seat 28 to provide a valve having an adjustable opening threshold pressure. Accordingly, the Applicant respectfully submits that one skilled in the art would not have a reason to combine the cited references in the manner claimed without the use of hindsight reasoning.

The Applicant further respectfully points out to the Examiner that claims 2-5 and 7-18 include many elements not taught nor suggested by any of the references cited by the Examiner. Accordingly, the Applicant respectfully requests substantive examination of the dependent claims and statements describing the reasons for rejection if such rejections are made in future actions.

Based on the aforementioned arguments, the Applicant respectfully requests withdrawal of the § 103 rejections and that the Examiner pass the case to allowance.

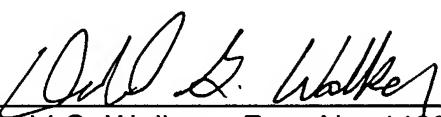
#### CONCLUSION

All of the grounds of rejection have been properly traversed, accommodated, or rendered moot. The Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding office action, and as such, the present application is in condition for allowance.

If it is believed that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600. Prompt and favorable consideration of this amendment is respectfully requested.

Respectfully submitted,

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